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EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

03/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Detailed Action

This action is in response to Applicant's arguments and notice of appeal submitted February 5, 2009.

11. Applicant's arguments and request for reconsideration, submitted February 5, 2009, have been fully considered and not found to be persuasive to remove the rejections of record in the previous office action. Applicant argues that the cited prior art does not render the claims obvious because there is no reason to objectively combine the teachings of the prior art. According to *KSR vs. Teleflex*, a modification to the prior art is obvious when it involves choice among a number of identifiable, predictable solutions. In the instant case, the disclosure by Remington of a number of different pharmaceutically acceptable counterions constitutes such a listing of identifiable, predictable solutions. One of ordinary skill in the art would thus have found it obvious to select among these prior art counterions. Furthermore, Berge and Remington disclose methods used in the art to develop pharmaceutically acceptable salts for known compounds, further indicating the predictability and expectation of success for one of ordinary skill in the art to choose an acceptable salt. According to Remington, the evaluation and creation of appropriate pharmaceutical salts is a routine part of adapting a drug for clinical use. Therefore one of ordinary skill in the art would be motivated to make and evaluate pharmaceutical salts for any acidic or basic drug. Applicant's arguments with respect to the need for "identified, predictable solutions" are not seen to apply in this instance because the selection of a counterion is not as unpredictable as

the selection of an active drug molecule. While substitution of a functional group on a main drug molecule is likely to greatly alter the function of said molecule, substitution of one known counterion for another is not likely to produce a drastic effect in the function of the drug as these counterions are known to be physiologically tolerated and inert. While the pharmaceutical art is often less predictable than examples in other arts, this unpredictability does not apply to this case because of the predictability of the known counterions.

Applicant further argues that the claimed hydrobromide salt is unpredictable. Specifically, Applicant points to its greater stability as an indication of unexpected results. However, increased stability is not considered to be an unexpected result that distinguishes a compound from the prior art. As stated in the previous final rejection, the court in *Pfizer vs. Apotex* found that not only is the selection of a particular salt of a known drug obvious, but the disclosure by Applicant of increased stability and shelf life of a particular salt is not sufficient to demonstrate unexpected results or to overcome a *prima facie* case of obviousness. Applicant's cited examples, such as *Eisai Co. v. Dr. Reddy's Laboratories Ltd.*, are not persuasive in the indicated context because they concern structural modifications to chemical compounds, which are less predictable than the instantly claimed counterion substitutions.

Therefore all rejections of record in the previous office action re maintained.

Applicant's remarks filed on February 5, 2009 after FINAL with respect to the rejections of record in the previous office action have been fully considered but are unpersuasive as discussed in the Final rejection and herein.

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/

Examiner, Art Unit 1623

3/13/2009

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623